

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS**

DANIEL F. BARKER,
LUCILLE F. BRAGG,
PAMELA CAMERON,
PEGGY DVORAK,
HENRY HARRIS,
ROBERT ARDEN HAYS,
RODNEY HERRMANN,
SHERRY HOOD,
DONNA CUMMINGS HOWARTH,
AARON HUMPHRIES,
SHANE JONES,
RONALD LAGOE,
ROBERT MATTHEW,
ROBBIE McNEIL,
JUSTIN L. MORRIS,
NICK D. MYERS,
ANDREW OPPELT,
VALERIE ORDAN,
ANNETTE PURCELL,
CURT RALSTIN,
NICOLE REDMOND,
SHELLI L. RICH,
MARIE RODRIGUEZ,
JAMES SIMPTON,
HADLEY S. SMITH,
SUSAN SMITH,
VICKY A. STOCKMAN,
SHIRLEY SWANNER,
JOHN VANN,
SUSAN E. VIARS,
JUDITHA WAYNE,
BONNIE WEDGEWORTH,
JEFFREY WILLIAMS,
Plaintiffs.

Civil Action No. _____

DEMAND FOR JURY TRIAL

VS.

**DAVOL, INC., and C. R. BARD, INC.,
Defendants.**

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COMPLAINT

Plaintiffs, DANIEL F. BARKER, LUCILLE F. BRAGG, PAMELA CAMERON, PEGGY DVORAK, HENRY HARRIS, ROBERT ARDEN HAYS, RODNEY HERRMANN, SHERRY HOOD, DONNA CUMMINGS HOWARTH, AARON HUMPHRIES, SHANE JONES, RONALD LAGOE, ROBERT MATTHEW, ROBBIE McNEIL, JUSTIN L. MORRIS, NICK D. MYERS, ANDREW OPPELT, VALERIE ORDAN, ANNETTE PURCELL, CURT RALSTIN, NICOLE REDMOND, SHELLI L. RICH, MARIE RODRIGUEZ, JAMES SIMPTON, HADLEY S. SMITH, SUSAN SMITH, VICKY A. STOCKMAN, SHIRLEY SWANNER, JOHN VANN, SUSAN E. VIARS, JUDITHA WAYNE, BONNIE WEDGEWORTH and JEFFREY WILLIAMS, by and through their attorneys, bring this action alleging the following, upon information and belief:

NATURE OF THE ACTION

1. Plaintiffs bring this action against C. R. BARD, INC. (hereinafter "BARD") and its wholly owned subsidiary, DAVOL, INC., (hereinafter "DAVOL"), for their sale and distribution of defective Composix® Kugel® Mesh Patches, (hereinafter "Kugel Patch"). The Defendants' defective product has been surgically implanted into the bodies of the Plaintiffs. The Kugel Patch presents, and will continue to present, a substantial risk of injury or death to the Plaintiffs. As a result, Plaintiffs have been injured and will need continual and ongoing medical monitoring.

PARTIES

2. Plaintiff, DANIEL F. BARKER, is an individual citizen and resident of the County of Lorain, State of Ohio. During the relevant time period, Plaintiff had hernia repair surgery

which included the implantation of a Kugel Patch into his body.

3. Plaintiff, LUCILLE F. BRAGG, is an individual citizen and resident of the County of Niagara, State of New York. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
4. Plaintiff, PAMELA CAMERON, is an individual citizen and a resident of the County of Wood, State of Texas. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
5. Plaintiff, PEGGY DVORAK, is an individual citizen and a resident of the County of Cochise, State of Missouri. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
6. Plaintiff, HENRY HARRIS, is an individual and a resident of the County of Anderson, State of Texas. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
7. Plaintiff, ROBERT ARDEN HAYS, is an individual and a resident of the County of Bastrop, State of Texas. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
8. Plaintiff, RODNEY HERRMANN, is an individual and a resident of the County of Pearl River, State of Mississippi. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
9. Plaintiff, SHERRY HOOD, is an individual and a resident of the County of Baltimore, State of Maryland. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.

10. Plaintiff, DONNA CUMMINGS HOWARTH, is an individual and a resident of the County of Hillsborough, State of Florida. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
11. Plaintiff, AARON HUMPHRIES, is an individual and a resident of the County of Cumberland, State of Maine. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
12. Plaintiff, SHANE JONES, is an individual and a resident of the County of Jefferson, State of Louisiana. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
13. Plaintiff, RONALD LAGOE, is an individual and a resident of the County of Virginia Beach, State of Virginia. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
14. Plaintiff, ROBERT MATTHEW, is an individual and a resident of the County of Jefferson, State of Missouri. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
15. Plaintiff, ROBBIE McNEIL, is an individual and a resident of the County of Cass, State of Michigan. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
16. Plaintiff, JUSTIN L. MORRIS, is an individual and a resident of the County of Douglas, State of Oregon. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
17. Plaintiff, NICK D. MYERS, is an individual and a resident of the County of Whitley,

State of Indiana. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.

18. Plaintiff, ANDREW OPPELT, is an individual and a resident of the County of Lee, State of Florida. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
19. Plaintiff, VALERIE ORDAN, is an individual and a resident of the County of Fayette, State of Ohio. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
20. Plaintiff, ANNETTE PURCELL, is an individual and a resident of the County of Monroe, State of Pennsylvania. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
21. Plaintiff, CURT RALSTIN, is an individual and a resident of the County of Nez Perce, State of Idaho. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
22. Plaintiff, NICOLE REDMOND, is an individual and a resident of the County of Rockwell, State of Texas. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
23. Plaintiff, SHELLI L. RICH, is an individual and a resident of the County of Los Angeles, State of California. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
24. Plaintiff, MARIE RODRIGUEZ, is an individual and a resident of the County of San Bernardino, State of California. During the relevant time period, Plaintiff had hernia

repair surgery which included the implantation of a Kugel Patch into her body.

25. Plaintiff, JAMES SIMPTON, is an individual and a resident of the County of Los Angeles, State of California. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
26. Plaintiff, HADLEY S. SMITH, is an individual and a resident of the County of Orleans, State of Louisiana. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
27. Plaintiff, SUSAN SMITH, is an individual and a resident of the County of Kanawha, State of West Virginia. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
28. Plaintiff, VICKY A. STOCKMAN, is an individual and a resident of the County of Clay, State of Missouri. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
29. Plaintiff, SHIRLEY SWANNER, is an individual and a resident of the County of Liberty, State of Texas. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
30. Plaintiff, JOHN VANN, is an individual and a resident of the County of Jackson, State of Missouri. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
31. Plaintiff, SUSAN E. VIARS, is an individual and a resident of the County of Washington, State of Mississippi. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.

32. Plaintiff, JUDITHA WAYNE, is an individual and a resident of the County of Taylor, State of Texas. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
33. Plaintiff, BONNIE WEDGEWORTH, is an individual and a resident of the County of Warren, State of Mississippi. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into her body.
34. Plaintiff, JEFFREY WILLIAMS, is an individual and a resident of the County of St. Clair, State of Illinois. During the relevant time period, Plaintiff had hernia repair surgery which included the implantation of a Kugel Patch into his body.
35. Defendant, DAVOL, INC., (hereinafter "DAVOL") is and was a wholly owned subsidiary of C. R. BARD, INC., with its principal place of business at 100 Sockanosset Crossroads, P.O. Box 8500, Cranston, Rhode Island, 02920, County of Providence. DAVOL has a registered agent in Rhode Island at CT Corporation System, 10 Weybosset Street, Providence, Rhode Island 02903. At all times relevant, DAVOL was a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business for manufacturing hernia surgical repair products in Cranston, Rhode Island. DAVOL designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the States of California, Florida, Idaho, Illinois, Indiana, Louisiana, Maine, Maryland, Michigan, Mississippi, Missouri, New York, Ohio, Oregon, Pennsylvania, Virginia, West Virginia, Rhode Island

and Texas.

36. Defendant, C. R. BARD, INC., (hereinafter "BARD") is a New Jersey corporation with its principal office and place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, County of Union, and at all times relevant designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the States of California, Florida, Idaho, Illinois, Indiana, Louisiana, Maine, Maryland, Michigan, Mississippi, Missouri, New York, Ohio, Oregon, Pennsylvania, Virginia, West Virginia, Rhode Island and Texas.

JURISDICTION AND VENUE

37. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). Plaintiff and no Defendant is a citizen of the same state as Plaintiff and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.
38. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(c) because Defendants are corporations. A corporation is deemed to reside in any judicial district where its contacts would be sufficient to subject it to personal jurisdiction at the time the action is commenced. DAVOL and BARD distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners at all times relevant and including the day this action is commenced, certain hernia surgical repair products to be surgically implanted in patients in the State of Texas, and more particularly within the jurisdictional boundaries of the United States District

Court for the Southern District of Texas.

GENERAL ALLEGATIONS

39. Plaintiffs' actions involve the Kugel Patch manufactured by Defendants between 2001 and March 2006. These Kugel Patches were sold by Defendants for implantation in patients in the course of hernia repair surgery.
40. A hernia occurs when the stomach muscles are too weak to contain the intestines, and as a result, a rupture occurs in the muscle wall which allows the intestines to protrude. The Kugel Patch was designed to treat ventral hernias caused by the thinning or stretching of scar tissue that forms after surgery.
41. The Kugel Mesh line of products was first manufactured by Surgical Sense, Inc., starting in or around 1996. In January of 2000, BARD acquired the Kugel line of hernia repair products from Surgical Sense, Inc. Shortly thereafter, in 2001, BARD introduced the Kugel Patch through its subsidiary, DAVOL.
42. The Kugel Patch, invented by Robert D. Kugel, M. D., is a polypropylene mesh prosthetic device developed to repair ventral hernias, or hernias of the abdominal region. The Kugel Patch is inserted behind the hernia defect in the abdomen through a small incision. In order to fit through the small incision the mesh is folded in half. Once inside the abdomen the mesh re-deploys as a result of a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh.
43. Due to defects in the design and manufacturing of the Kugel Patch, the "memory recoil ring" that opens the patch can break under the stress of placement of the product in the intra-abdominal space. Once the memory recoil ring has broken, it can later come loose

and cause serious injuries as it travels through the body. These injuries include: intestinal perforations; ring migration through the abdominal wall; abscesses; bowel obstruction and sepsis; and chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

44. The Kugel Patches present and constitute an unreasonable risk of danger and injury in the following respects:
 - a. the memory recoil ring of the Kugel Patch is likely to malfunction after being implanted;
 - b. the Kugel Patch was not properly manufactured;
 - c. the Kugel Patch was defectively designed;
 - d. the Kugel Patch did not perform as safely as an ordinary consumer/patient would expect;
 - e. the Kugel Patch was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and
 - f. such further and additional defects as discovery and the evidence reveal.
45. As a result of this dangerous and defective condition, and the numerous serious injuries that resulted, the FDA issued the first Class 1 Recall of various lots of the Kugel Patches on December 22, 2005. The Class 1 Recall was expanded in subsequent recalls on March 31, 2006, and January 24, 2007. A Class 1 Recall is the highest level of recall available to the FDA. It is issued when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death.
46. The products that are affected by the recall were distributed to customers and implanted

in patients worldwide. As of March 2006, roughly 75,000 Kugel Patches had been sold, Upon information and belief, the vast majority of the patches which have been implanted are currently still inside patients residing in the United States.

47. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.
48. Defendants' Kugel Patches are defective because they possess the potential for breakage or malfunction of the memory recoil ring and, as a result, are subject to risk of resulting injury.
49. Defendants did not timely apprise the public and physicians of the defect in their Kugel Patches, despite Defendants' knowledge that memory recoil rings had failed due to the described defects. Defendants' concealment of a known defect from Plaintiffs tolls the applicable statute of limitation. Plaintiffs could not have discovered the existence of the defect in the Kugel Patch implanted in them until at least December 22, 2005, when Defendants first provided notice of the recall.
50. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.
51. As a direct and proximate cause of Defendants' conduct and the recalled Kugel Patches,

Plaintiffs have suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiffs will incur future medical costs related to the recalled Kugel Patches.

PLAINTIFFS' EXPERIENCES

52. Plaintiffs underwent hernia repair surgical procedures at various times during the relevant period, and during the course thereof, their physicians implanted hernia repair patch into their bodies.
53. The Kugel Patches implanted in Plaintiffs were designed, manufactured, sold and distributed by Defendants, and were intended to be used by surgeons for hernia repair surgeries. Defendants represented the Kugel Patch to be an appropriate and suitable product for such purposes.
54. The Kugel Patches inserted in Plaintiffs' bodies have caused them severe pain and suffering and mental anguish and will continue to do so into the future.
55. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Kugel Patch, Plaintiffs sustained, and will continue to sustain, injuries and damages.

COUNT I

(Unfair And Deceptive Trade Practices)

56. Plaintiffs allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.
57. At all times relevant, Defendants were engaged in the design, manufacturing, assembling, distributing, conveying and/or selling of the Kugel Patch in their ordinary course of

business. Defendants designed, manufactured, assembled and sold the devices to hospitals and physicians, knowing that they would be thereby sold to patients who needed hernia repair surgery, including Plaintiffs.

58. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the Kugel Patches.
59. Plaintiffs are consumers of the defective product and were injured by Defendants' deceptive and unfair acts.
60. Had the Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Kugel Patch, would not have incurred related medical costs and would not continue to incur these costs.
61. Defendants' representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts or practices in violation of the consumer protection statutes of one or more of the States of Alabama, Arkansas, Florida, Illinois, Louisiana, Massachusetts, Maryland, Mississippi, Nevada, New York, Oklahoma, Tennessee, Utah, West Virginia, Rhode Island, Texas, and the States of residence of the Defendants.
62. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiffs for the Kugel Patch and/or for the costs of removing and/or replacing the Kugel Patch that they would not have paid had Defendants not engaged in unfair and deceptive conduct.
63. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The purpose of that conduct, directed at patients, physicians and consumers, was to create

demand for and to sell the Kugel Patches. Each aspect of Defendants' conduct combined to artificially create sales of the Kugel Patches.

64. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have incurred and will likely continue to incur medical costs relating to the Kugel Patch, including medical monitoring and/or other hospital costs, in an amount to be proven at trial.
65. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs are entitled to injunctive relief in the form of a court supervised medical monitoring program, punitive damages, attorneys fees, and costs of suit.
66. Medical monitoring is medically reasonable and necessary in order to provide for the early detection and prevention of irreparable harm, severe and debilitating injuries and death. In the absence of such relief, Plaintiffs might not receive prompt medical care that could prolong his productive life, increase prospects for improvement and to minimize disability.

COUNT II

Negligence

67. Plaintiffs allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.
68. Defendants DAVOL and BARD were negligent to Plaintiffs in the following respects:
69. DAVOL and BARD at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Kugel Patch.

70. DAVOL and BARD at all times mentioned knew or in the exercise of reasonable care should have known that the Kugel Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Kugel Patch's users.
71. DAVOL and BARD so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Kugel Patch, that they were dangerous and unsafe for the use and purpose for which it was intended.
72. DAVOL and BARD were aware of the probable consequences of the Kugel Patch. DAVOL and BARD knew or should have known that the Kugel Patch would cause serious injury; they failed to disclose the known or knowable risks associated with the Kugel Patch. DAVOL and BARD willfully and deliberately failed to avoid those consequences, and in doing so, DAVOL and BARD acted in conscious disregard for the safety of Plaintiffs.
73. Defendants DAVOL and BARD owed a duty to Plaintiffs to adequately warn Plaintiffs and Plaintiffs' treating physicians of the risks of breakage, separation, tearing and splitting associated with the Kugel Patch and the resulting harm and risk it would cause patients.
74. Defendants DAVOL and BARD breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture,

inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Kugel Patch.

75. As a direct and proximate result of the duties breached, the Kugel Patch used in the Plaintiffs' hernia repair surgeries failed, resulting in Plaintiffs suffering pain and harm.
76. As a direct and proximate result of DAVOL's and BARD's negligence, Plaintiffs have suffered injuries and damages.
77. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

COUNT III

Strict Liability

78. Plaintiffs allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.
79. Defendants DAVOL and BARD are strictly liable to Plaintiffs in the following respects:
80. DAVOL and BARD designed, manufactured, assembled, distributed, conveyed and/or sold the Kugel Patch for hernia repair surgery.
81. The Kugel Patches subject to the Class I Recall were defective because they failed to perform safely and effectively for the purpose they were originally designed. Plaintiffs' Kugel Patch was a Class I recalled device that failed while in Plaintiffs' body, causing

Plaintiffs to develop serious physical complications which required subsequent, painful and unnecessary surgical removal of their Kugel Patches or the mental anguish of knowing they have a defective product inside their bodies.

82. At all times mentioned, the Kugel Patch was substantially in the same condition as when it left the possession of DAVOL.
83. The Kugel Patches implanted into Plaintiffs were being used in a manner reasonably anticipated at the time it was implanted in them by their surgeons.
84. The Kugel Patches, like those found in Plaintiffs, at the time they left the possession of DAVOL and BARD were inherently dangerous for their intended use and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to Plaintiffs as follows:
 - a. The Kugel Patch was sold in a defective condition by design and manufacture;
 - b. The Kugel Patch as designed and manufactured was unsafe to Plaintiffs;
 - c. The Kugel Patch as designed and manufactured was unreasonably dangerous to Plaintiffs;
 - d. The Kugel Patch did not perform safely as an ordinary consumer/patient, like Plaintiffs, would expect;
 - e. The Kugel Patch as designed and manufactured was unsafe for its intended use;
 - f. DAVOL and BARD failed to warn the end user about the dangers and risks of the product;

- g. DAVOL and BARD knew the component parts of the Kugel Patch as implemented through design and/or manufacture could cause injury to the end user;
- h. Failing to implement an adequate, safe and effective “memory recoil ring” and/or its interaction with the mesh of the Kugel Patch to withstand the foreseeable stresses they would be subject to within the intra-abdominal space;
- i. Failing to avoid migration of the Kugel Patch and/or its components from the initial site of the hernia repair surgery;
- j. Any other acts or failures to act by DAVOL or BARD regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of Kugel Patches for hernia repair surgery as will be learned during discovery.

85. DAVOL’s and BARD’s conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

COUNT IV

Intentional Infliction of Emotional Distress

86. Plaintiffs allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

87. Defendants DAVOL and BARD are liable to Plaintiffs for the intentional infliction of emotional distress in the following respects:
88. Plaintiffs suffered severe emotional distress, which was a result of DAVOL's and BARD's extreme, outrageous, intentional, willful, and reckless conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or sale of the Kugel Patch for hernia repair surgery.
89. Plaintiffs suffered severe emotional distress, which was as a result of DAVOL's and BARD's extreme, outrageous, intentional, willful, and reckless conduct in failing to adequately and safely design and construct an effective and safe Kugel Patch for hernia repair surgery, in complete and reckless disregard for the safety of Plaintiffs.
90. Therefore, DAVOL and BARD are liable to Plaintiffs.
91. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

COUNT V

Breach of Implied Warranty

92. Plaintiffs allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

93. Defendants DAVOL and BARD are liable to Plaintiffs for their breach of implied warranty in the following respects:
94. DAVOL and BARD sold the Kugel Patch which was implanted in the Plaintiffs. DAVOL and BARD impliedly warranted to Plaintiffs, Plaintiffs' physicians and healthcare providers, that the Kugel Patch was of merchantable quality and safe for the use for which it was intended.
95. DAVOL and BARD knew or should have known that the Kugel Patch at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.
96. Plaintiffs, Plaintiffs' physicians and health care providers reasonably relied on DAVOL's and BARD's judgment, indications and statements that the Kugel Patch was fit for such use.
97. When the Kugel Patch was distributed into the stream of commerce and sold by DAVOL and BARD, it was unsafe for its intended use, and not of merchantable quality, as warranted by DAVOL and BARD, in that it had very dangerous propensities when used as intended and implanted into a patient's body where it could cause serious injury of harm or death to the end user.
98. Plaintiffs suffered such injuries and damages as a result of DAVOL's and BARD's conduct and actions.

COUNT VI

Failure to Warn

99. Plaintiffs allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.
100. In the course of business, DAVOL and BARD designed, manufactured and sold the Kugel Patch to Plaintiffs' healthcare providers for hernia repair surgeries.
101. At the time of the design, manufacture and sale of the Kugel Patch, and more specifically at the time Plaintiffs received the Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further, the Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Kugel Patch.
102. BARD and DAVOL failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the products. BARD and DAVOL failed to warn of the known or knowable injuries associated with malfunction of the Kugel Patch, including but not limited to rupture of the Kugel Patch and severe peritonitis and infection which would require subsequent surgical procedures and could result in severe injuries.
103. The dangerous and defective conditions in the Kugel Patches existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiffs had their hernia repair surgeries, the Kugel Patch was in the same condition as when manufactured, distributed and sold.

104. Plaintiffs did not know at the time of use of the Kugel Patch, nor at any time prior thereto, of the existence of the defects in the Kugel Patches.
105. Plaintiffs suffered the aforementioned injuries and damages as a direct result of DAVOL's and BARD's failure to warn.
106. The conduct of DAVOL and BARD in continuing to market, promote, sell and distribute the Kugel Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter DAVOL, BARD and others from similar conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

- a. For all damages available to Plaintiffs under the law, including, but not limited to, past and future medical, lost wages in the past, loss wage-earning capacity in the future, pain and suffering in the past and future, mental anguish, and disfigurement;
- b. For an Order establishing a medical monitoring program, funded by Defendants, to provide medical testing, screening, services, research and education and a medical/legal registry to ensure that she receives prompt and proper medical treatment;
- c. For punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

- d. For all applicable statutory damages available to Plaintiffs under the consumer protection legislation of the States of California, Florida, Idaho, Illinois, Indiana, Louisiana, Maine, Maryland, Michigan, Mississippi, Missouri, New York, Ohio, Oregon, Pennsylvania, Virginia, West Virginia, Rhode Island, Texas, and the States of residence of the Defendants.
- e. For an award of attorneys' fees and costs;
- f. For prejudgment interest and the costs of suit; and
- g. For such other relief as this court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury in this case.

Dated: This 21st day of December, 2007.

David W. Alexander

David W. Alexander

Texas Bar No. 24029417

SDTX Bar No. 32900

Steven J. Kherkher

Texas Bar No. 11375950

SDTX Bar No. 12341

John T. Boundas

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